

Best Available Copy

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

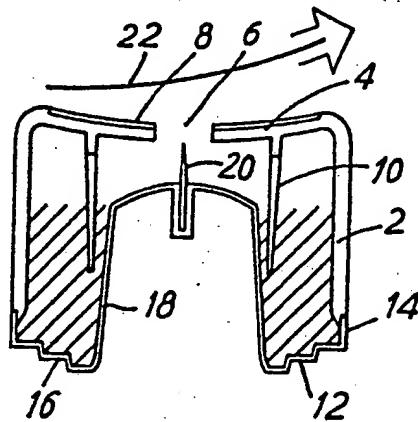


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | | |
|---|----|--|------------------------------|
| (51) International Patent Classification ⁴ : | | (11) International Publication Number: | WO 85/04089 |
| A61B 5/14; 17/32 | A1 | (43) International Publication Date: | 26 September 1985 (26.09.85) |

| | | | |
|--|--|-------------------------|---|
| (21) International Application Number: | PCT/GB85/00095 | (81) Designated States: | AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), HU, JP, LU (European patent), NL (European patent), NO, SE (European patent), US. |
| (22) International Filing Date: | 8 March 1985 (08.03.85) | | |
| (31) Priority Application Number: | 8406154 | | |
| (32) Priority Date: | 9 March 1984 (09.03.84) | | |
| (33) Priority Country: | GB | Published | <i>With international search report.</i> |
| (71)(72) Applicants and Inventors: | PALMER, Geoffrey, Charles [GB/GB]; 226 Watford Road, Harrow, Middlesex HA1 3TY (GB). RENFREW, Bruce, James [GB/GB]; 116 Regent Road, Leicester LE1 7LT (GB). | | |
| (74) Agent: | ENSKAT, Michael, Antony, Frank; Saunders & Dolleymore, 2 Norfolk Road, Rickmansworth, Hertfordshire WD3 1JH (GB). | | |

(54) Title: APPARATUS FOR SAMPLING A FLUID



(57) Abstract

Apparatus for sampling blood by puncturing a skin through which the blood can be obtained, includes a housing (2) providing a surface against which a human thumb (22) can be placed. An aperture (6) in said surface communicates with a chamber defined by the housing (2). A needle (20) is supported in said chamber. The base of the housing (2) is dome-shaped for imparting to the needle (20) when pressed beyond its point of inversion an acceleration in the direction of the aperture (6) to propel said needle (20) through the aperture (6) to puncture the skin, and subsequently to withdraw the needle (20) from the skin to enable blood to pass through the punctured skin into the chamber.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | |
|---------------------------------|---|-----------------------------|
| AT Austria | GA Gabon | MR Mauritania |
| AU Australia | GB United Kingdom | MW Malawi |
| BB Barbados | HU Hungary | NL Netherlands |
| BE Belgium | IT Italy | NO Norway |
| BG Bulgaria | JP Japan | RO Romania |
| BR Brazil | KP Democratic People's Republic of Korea | SD Sudan |
| CF Central African Republic | KR Republic of Korea | SE Sweden |
| CG Congo | LI Liechtenstein | SN Senegal |
| CH Switzerland | LK Sri Lanka | SU Soviet Union |
| CM Cameroon | LU Luxembourg | TD Chad |
| DE Germany, Federal Republic of | MC Monaco | TG Togo |
| DK Denmark | MG Madagascar | US United States of America |
| FI Finland | ML Mali | |
| FR France | | |

-1-

APPARATUS FOR SAMPLING A FLUID

The present invention relates to apparatus for sampling a fluid, for example, for sampling and testing blood for a predetermined condition.

5 Kits for sampling and testing blood for diagnosing diabetes are known. Such kits employ a gadget for firing a needle to pierce the skin of the patient and a separate container holding a cocktail mixture into which blood from the patients pierced skin can be dripped. The colour of the cocktail mixture when blood is added will indicate the 10 likelihood of the patient having a diabetic condition.

15 The disadvantage of this arrangement is that the kit is cumbersome to operate and the procedures to be adopted are not always clearly understood by the patient who normally has to operate the kit himself based on the written instructions accompanying the kit.

20 Furthermore, the gadget for piercing the skin is somewhat of a fearsome device in that it involves a trigger for releasing a spring loaded needle which upon release is directed at high speed into the skin in full view of the patient. This is 25 often off-putting to the user.

According to the present invention there is provided apparatus for sampling a fluid by puncturing a skin through which said fluid can be obtained, the apparatus comprising a housing having a roof providing a surface for contacting said skin, an aperture in said roof communicating with a chamber defined by the housing, a needle supported in said chamber and means for imparting to said needle an acceleration in the direction of said aperture to 30 propel said needle through the aperture to puncture 35

-2-

the skin, and subsequently to withdraw the needle from the skin to enable said fluid to pass through the punctured skin into the chamber.

According to the present invention there is
5 further provided apparatus for puncturing a skin comprising a housing having a roof defining a surface arranged to engage an area of skin to be punctured, an opening in said roof, a needle mounted in said housing for movement towards and through said opening and propulsion means operable when actuated to apply 10 a propelling force to the needle to drive the needle partially through the opening to puncture any skin placed on said surface.

Blood sampling and testing apparatus
15 embodying the invention will now be described, by way of example only, with reference to the accompanying diagrammatic drawings, in which:

Figures 1 to 4 are sections through a first embodiment of the invention at four different stages 20 during the operation of the apparatus; and

Figures 5 to 8 are sections through a second embodiment of the invention at four different stages during the operation of the apparatus.

The blood sampling and testing apparatus or
25 unit shown in Figure 1 is arranged to sample the blood of a patient and to test it to ascertain whether or not the patient has a diabetic condition. The apparatus is in the form of a disposable unit so that once a sample of blood has been taken and tested 30 the unit may be discarded.

As shown in Figures 1 to 4 the unit comprises an inverted cylindrical transparent container 2 with an open base and a concave opaque roof 4. The roof 4 has a central aperture 6 and an array of radially directed, equiangularly spaced

-3-

grooves 8 in the outer surface thereof, each groove 8 communicating with the central aperture 6.

Advantageously the grooves 8 may be three in number.

The roof 4 supports a downwardly depending

5 cylindrical guide member 10 having an axial length equal to just over one half of the axial length of the container 2.

The lower extremity of the container 2 is of reduced external diameter to receive a cap member

10 12. The cap member 12 has a rim 14 which is arranged to engage the lower extremity of the container 2 and is provided with a plurality of concentric annular steps 16 which terminate in a central thimble-shaped protrusion 18. When the cap member 12 is mounted on
15 the container 4, the protrusion 18 extends into the cylindrical guide 10 which guide acts to constrain the protrusion 18 for movement along its longitudinal axis. The head of the protrusion 18 supports the end portion of a hypodermic needle 20 which is mounted
20 so as to be in alignment with the central aperture 6 in the roof 4 of the container 2. The needle 20 can be embedded in the protrusion.

The container 4 is of rigid plastics while the cap 12 is of flexible plastics.

25 When assembled, the cap member 12 is adhesively secured or heat-sealed to the container 4 and the container 4 is at least partially filled with an enzyme cocktail suitable for detecting a diabetic condition. A flexible disk 22 coated with a pressure
30 sensitive adhesive is placed on the roof 4 to seal the grooves 8 and the aperture 6 against the egress of liquid from the container 4. The disk 22 is advantageously provided with a tab (not shown) to enable the disk to be readily stripped off the roof 4
35 when needed for use.

-4-

In operation a patient grasps the tab of the disk and strips it from the roof 4 to provide open access to the cocktail within the container 2 through the aperture 6.

5 The patient then places his thumb 24 or some other part of his anatomy from which blood is to be drawn, on to the concave roof 4. Then using a free finger the patient applies pressure to the cap member 12 to push the thimble-shaped protrusion 18 inwardly.
10

The stepped portion 16 of the cap initially offers increasing resistance to the applied pressure until it is deformed to an extent where it starts to undergo an inversion. At this point, resistance to pressure decreases rapidly with the consequent effect that the protrusion 18 is accelerated towards the roof 4. The needle 20 which is rigid with the protrusion 18 undergoes the same acceleration to which the protrusion 18 is subjected and is projected 20 through the aperture 6 into the skin of the patient (see Figure 2). The movement of the needle 20 is halted when the protrusion 18 strikes the underside of the roof 4.

25 As the thimble-shaped protrusion is displaced inwardly the volume of the container is reduced and the free air and also possibly some liquid will tend to be expelled through the aperture 6. Because the thumb is blocking the aperture the grooves 8 provide an escape route for this excess air and liquid.
30

When the pressure on the cap member 12 is released the cap member 12 will recover under its natural resilience and accordingly the protrusion 18 will withdraw the needle 20 from the skin.

35 As the cap member 12 returns to its

-5-

original configuration (see Figure 3) blood will drip from the pierced skin through the aperture 6 into the cocktail within the container. When a sufficient quantity of blood has been released into the
5 container 2 the pressure adhesive disk 22 is replaced (see Figure 4) and the unit shaken to ensure good mixing. The colour of the cocktail will then indicate the result of the test. Once the result of the test has been noted the now sealed unit is
10 discarded. A new unit is required for a fresh test.

It will be appreciated that the pressure of the thumb on the roof 4 will cause that part of the thumb exposed by the aperture 6 to bulge to provide a "pinch effect". This effect is particularly
15 advantageous since when skin is pinched prior to the insertion of a needle the pain threshold of the patient in the pinched area is increased.

In order to achieve a good "pinch effect" the ratio of the area of the roof to the area of the
20 opening is preferably less than 10:1 but not greater than 20:1.

In the apparatus or unit shown in Figures 5 to 8 parts similar to those in Figures 1 to 4 are similarly referenced.

25 As shown, the container 2 has adjacent its lower end an inwardly directed annular flange 30. On the underside of the roof 4 instead of the cylindrical guide of Figure 1 an annular abutment member or stop 32 is provided.

30 A spiral helical spring 28 compressed into a planar configuration is shown in Figure 5. The radially outer turn of the spring 28 is secured (for example by an adhesive) to the underside of the flange 30. The radially inner turn of the spring 28
35 supports a platform 34 carrying a needle 20.

-6-

The underside of the platform 34 supports a retaining ring 36 defining a circumferentially extending retaining groove 38.

5 The cap member 12 instead of defining a thimble-shaped protrusion as with the cap member of Figure 1 defines a small inwardly directed centering dimple 40.

10 On the inner face of the cap member 12 in spaced apart relationship are a pair of upstanding gripping fingers 42. The tip of each gripping finger has a projection 42a which is arranged to engage the groove 38 in the annular member and so hold the platform 34 in position against the bias of the spring 28.

15 The spring when in its relaxed state adopts the configuration shown in Figure 7.

In operation the procedure adopted in obtaining a blood sample is generally as hereinbefore described with reference to Figures 1 to 4. When, 20 however, pressure is applied to the cap member 12 the curvature developed by the cap member will cause the two fingers 42 to become inclined away from one another so that their tips 42a become disengaged from the groove 38 in the annular flange 36. The spring 25 force of the spring 28 is now released whereupon the platform 34 and needle 20 are propelled towards the aperture 6. The displacement of the platform 34 is halted when it abuts the stop 32 (see Figure 6) and this limits the penetration of the needle into the skin.

30 Because the spring has been released so suddenly it will overshoot its mean position so consequently once the skin has been pierced the needle will be retracted by the spring and eventually settle in the position indicated in Figure 7.

-7-

Once sufficient blood has been drawn, the unit is resealed with the disk 22 (as indicated in Figure 8) and after the test results have been noted is discarded.

5 While the arrangement described is suitable for drawing blood from a patient it will be appreciated that the arrangement can be readily adapted to introduce liquids into the blood of a patient for purposes of innoculation for example.

10 The needle is preferably arranged to be hollow and modifications would need to be made to ensure that no air from the container enters the patient.

15 It will also be appreciated that different patients have different thicknesses and toughneses of skin, accordingly needles of different length may be used and the force applied to the needle varied.

Units with different properties in this respect may be colour coded with different colours for easy identification.

20 It will also be appreciated that the units described are not limited for use in testing for a diabetic condition but can be used to test for other conditions or merely for obtaining a blood sample supported in a preserving environment for use in subsequent tests.

25 It will further be appreciated that said cap member 12 may be of dome-shaped configuration instead of the stepped configuration shown in the drawings.

30 It will be appreciated that the needle and the spring can both be of plastics material or a composite of plastics and other material.

35 Also while it is important that the roof should be opaque to hide the needle from the patient's view the housing may also be opaque but be

-8-

provided with a small viewing window to enable the fluid in the container to be inspected without exposing the needle to the viewer.

-9-

CLAIMS

1. Apparatus for puncturing a skin comprising a housing having a roof defining a surface arranged to engage an area of skin to be punctured, an opening 5 in said roof, a needle mounted in said housing for movement towards and through said opening and propulsion means operable when actuated to apply a propelling force to the needle to drive the needle partially through the opening to puncture any skin 10 placed on said surface.
2. Apparatus according to claim 1, wherein said propulsion means is arranged also to retract the needle back through the opening following its initial displacement therethrough.
- 15 3. Apparatus according to claim 1 or to claim 2, wherein said propulsion means are formed by a flexible wall of the housing.
4. Apparatus according to claim 3, wherein said flexible wall is generally dome-shaped.
- 20 5. Apparatus according to claim 3, wherein said flexible wall is of generally stepped dome-shape.
6. Apparatus according to claim 1 or to claim 2, wherein said propulsion means comprises a coiled 25 spring.
7. Apparatus for sampling a fluid by puncturing a skin through which said fluid can be obtained, the apparatus comprising a housing having a roof providing a surface for contacting said skin, an aperture in said surface communicating with a chamber defined by the housing, a needle supported in said chamber and means for imparting to said needle an acceleration in the direction of said aperture to propel said needle through the aperture to puncture 30 the skin, and subsequently to withdraw the needle 35

-10-

from the skin to enable said fluid to pass through the punctured skin.

8. Apparatus according to claim 7, wherein the chamber contains a testing substance to effect a test 5 on the fluid when it is caused to enter the chamber.

9. Apparatus according to claim 7 or to claim 8, wherein the acceleration imparting means comprises a flexible cap member of predetermined configuration carrying said needle, said predetermined 10 configuration being such that when pressure is applied to said cap member in a direction to displace said needle towards the aperture, the resistance of said cap member to displacement will increase progressively to a point at which inversion occurs 15 and thereafter the resistance to pressure progressively decreases.

10. Apparatus according to claim 9, wherein the flexible cap member is of concentric stepped configuration.

20 11. Apparatus according to claim 7 or to claim 8, wherein the acceleration imparting means comprises a compressed spring carrying said needle, and trigger means for releasing the force of the spring.

12. Apparatus according to claim 11, wherein 25 the trigger means comprises a pair of spaced fingers mounted on said cap in spaced apart relationship, said fingers being arranged to hold said spring in its compressed state, the displacement of the cap being arranged to effect change in the curvature of 30 the cap such that said fingers are moved apart to release said spring.

13. Apparatus according to any preceding claim, wherein said surface is provided with grooves to provide a passage between said surface and said skin 35 to and from the aperture or opening.

-11-

14. Apparatus according to any preceding claim wherein the said surface is concave.
15. Apparatus according to any preceding claim, said apparatus being substantially the same order of
5 size as a human thumb.

1/2

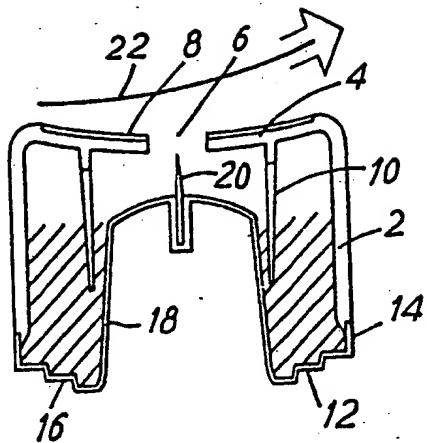


FIG. 1

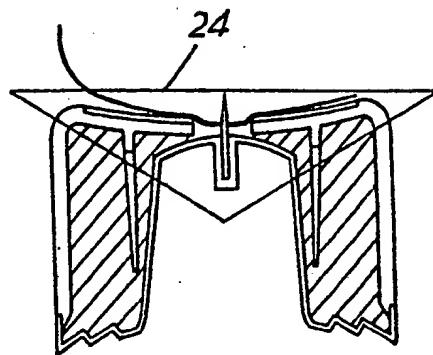


FIG. 2

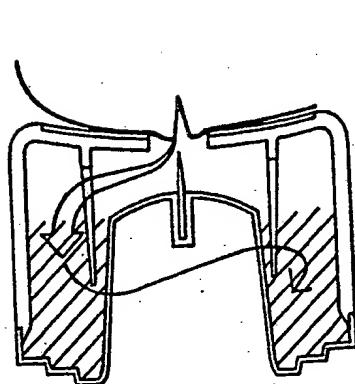


FIG. 3

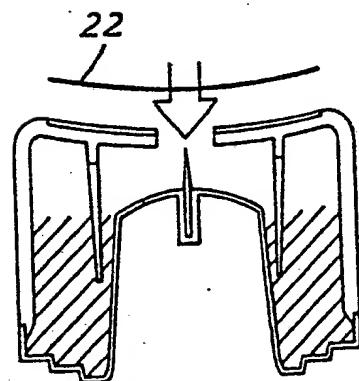


FIG. 4

2/2

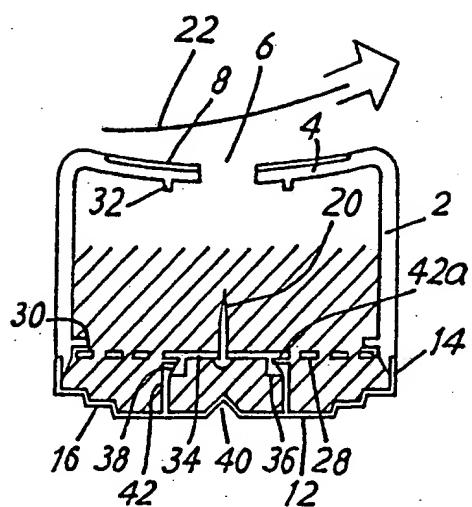


FIG. 5

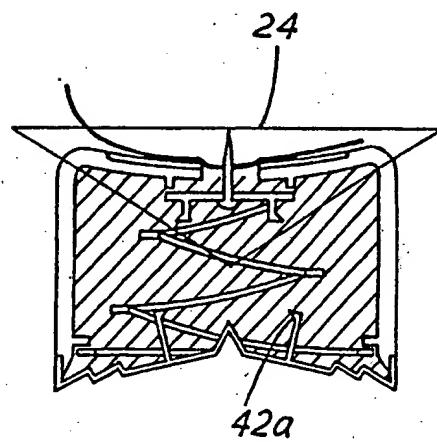


FIG. 6

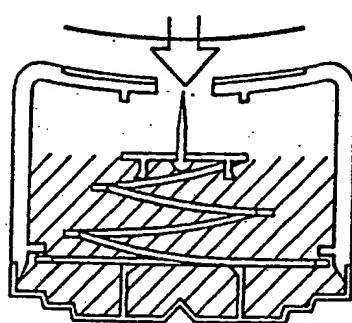


FIG. 7

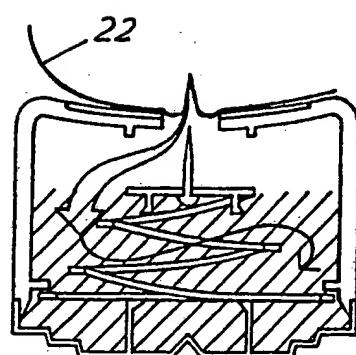


FIG. 8

INTERNATIONAL SEARCH REPORT

PCT/GB 85/00095

International Application No.

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC⁴: A 61 B 5/14; A 61 B 17/32

II. FIELDS SEARCHED

Minimum Documentation Searched⁷

| Classification System | Classification Symbols |
|-----------------------|------------------------|
| IPC ⁴ | A 61 B; A 61 M |

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched⁸III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹

| Category ¹⁰ | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ |
|------------------------|--|-------------------------------------|
| X | US, A, 4416279 (J.A. LINDNER et al.) 22 November 1983 see abstract; column 1, line 61 - column 2, line 21; column 3, lines 10-28; figures 1-11 -- | 1,2,6,7,11, 14,15 |
| X | EP, A, 0097748 (G.J. SLAMA) 11 January 1984 see abstract; page 4, line 20 - page 5, line 22; page 6, line 27 - page 7, line 7; figures 1-5 -- | 1,2,6-8,11, 15 |
| X | US, A, 4375815 (J.A. BURNS) 8 March 1983 see abstract; column 1, lines 33-65; column 3, line 65 - column 4, line 17; figures 1-6 -- | 1,2,6,7,11, 12,15 |
| X | US, A, 3741197 (M.C. SANZ et al.) 26 June 1973 see abstract; column 2, lines 21-36; column 3, line 25 - column 4, line 7; figures 1,3,5 -- | 1-4,6,7,9, 11,13-15 . /. |

¹⁰ Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

¹¹ "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention¹² "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step¹³ "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.¹⁴ "A" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

4th June 1985

Date of Mailing of this International Search Report

26 JUIN 1985

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

G.L.M. Kruydenberg

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

| Category * | Citation of Document, with indication, where appropriate, of the relevant passages | Relevant to Claim No |
|------------|--|----------------------|
| A | US, A, 3236237 (R.P. DUNMIRE) 22 February 1966 see column 3, lines 24-36, 47-53; column 4, lines 21-44; column 5, line 64 - column 6, line 15; figures 1-5 ----- | 1,3-5,9,10, 14 |
| A | US, A, 3094121 (W.K. BLUMENSTEIN et al.) 18 June 1963 see column 1, lines 34-45; column 3, lines 48-64; figures 1-8 ----- | 1,3-5,9,10 |

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/GB 8500095 (SA 8954)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 19/06/85

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|--|---------------------|----------------------------|---------------------|
| US-A- 4416279 | 22/11/83 | None | |
| EP-A- 0097748 | 11/01/84 | None | |
| US-A- 4375815 | 08/03/83 | None | |
| US-A- 3741197 | 26/06/73 | CH-A- 538277 | 15/08/73 |
| US-A- 3236237 | | None | |
| US-A- 3094121 | | None | |

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)